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10/814,981	03/30/2004	Tae-Woong Koo	2158/0206747-US0	8675
7278	7590	10/18/2007	EXAMINER	
DARBY & DARBY P.C.			DO, PENSEE T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/814,981

Applicant(s)

KOO ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/26/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Appeal Brief

The appeal brief filed on December 22, 2006 has been acknowledged and entered.

Prosecution is now re-opened as followed:

Amendment Entry & Claims Status

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The after-final amendment filed on April 7, 2006 is entered.

Claims 1-16, 19-34 are pending.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph in the final rejection is withdrawn herein.

Rejections under 102 and 103 in the final rejection are withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-10, 13-16, 19, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by West et al. (US 6,699,724- issued on March 2, 2004; filed on July 14, 2000).

West et al. teaches a method of assay comprising: associating the first unlabeled binding pair member with a surface-enhanced Raman scattering-active particle (gold nanoparticle/nanoshell); contacting the first unlabeled binding pair member with the gold nanoparticle/nanoshell with a second unlabeled binding pair member and detecting the difference in SERS signal before and after adding the second binding pair member. (see fig. 8A-8C; col. 15, line 1-29). For claims 2 and 4, the SERS active particle is a metal particle such as gold. (see fig. 8A-8C; col. 15, line 1-29). For claim 3, the conjugation of the first binding member to the SERS active surface is by adsorption. (see col. 11, lines 29-30). Regarding claims 6-8, since West teaches the same method with the same reagents, the result would be the same, i.e. increase or decrease in SERS signal or dissociation of the first binding member from the metal particles. For claim 9, adsorption is detected before the second binding pair member is contacted with the first binding member. (see col. 15, lines 17-19). For claim 10, since the metal particle is used as SERS signal enhancement, it is inherent that the SERS signal is increase when the first binding member is absorbed onto the metal particle. For claims 13-16, West teaches that the first and second binding members are proteins such as antibody and antigens, receptor and ligand, nucleic acid and protein (see col. 3, lines 30-34; col. 11, line 54). For claim 19, West teaches using a Raman spectroscopy for detection. (see col. 16, lines 15-16). For claim 20, the first binding member is

Art Unit: 1641

immobilized on the metal particle. (see col. 15, lines 3-4). West also teaches that the sample is serum. (see col. 4, line 53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 22-23, 25-28, 30, 31, 32, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over West et al. in view of Maine et al. (US 6,221,619).

West has been discussed above.

However, West fails to teach immobilizing the first binding pair member/antibody on an immobilizing substrate.

Maine teaches different assay formats comprising attaching antibody/antigen to a solid phase such as porous, non-porous materials, latex particles, magnetic particles, microparticles, beads, membranes, microtiter wells, and plastic tubes. One of the antibody/antigen reagents used in an immunoassay is attached to a signal-generating compound or label. This signal-generating compound is in itself detectable or may be reacted with one or more additional compounds to generate a detectable product. Detection systems is Raman spectroscopy. (see col. 9, line 52-col. 10, line 20).

It would have been obvious to one of ordinary skills in the art to immobilize the antibody/antigen to a solid phase such as magnetic particles, beads, etc. as taught by Maine before attaching to a signal generating compound such as colloidal metal

particles in the method of West because immobilization of the antibody/binder/antigen to a solid support before attaching the antibody/binder to colloidal metal particles for a surface enhanced scattering signal detection can capture the analyte and detect at the same time without using a second capture antibody.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over West in view of Fray (US 4,904,356).

West has been discussed above.

However, West fails to teach associating the metal particle to the first binding member in the present of a chemical salt such as lithium chloride.

Fray teaches using lithium chloride salt to as a salt of a metal surface to be refined. Such salt when saturating the metal surface allows the metal ions to move through freely. (see col. 1, lines 27-40).

It would have been obvious to one of ordinary skills in the art to use lithium chloride as taught by Fray as an enhancer for the metal surface in the assay mixture as in the method of West since this salt is used for refining metal surface and it keeps the metal ions on the metal surface intact or prevents the metal ions on the metal surface from being wear off. Since West's nanoshell is a metal nanoshell, such salt would advantageously prevent the metal of the nanoshell from being worn off.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over West in view of Gole et al. (US 6,589,883).

West has been discussed above.

However, West fails to teach the SERS active substrate is a porous silicon substrate comprising impregnated metals.

Gole teaches metalizing substrates such as porous silicon for use in Raman scattering detection. (see col. 1, line 60-col. 2, line 3; col. 3, lines 1-3; lines 34-42).

It would have been obvious to one of ordinary skills in the art to use porous silicon substrate coated with metals as a Raman-active substrate as taught in Gole in the method of West because high-surface area substrates such as porous silicon display a visible photoluminescence upon excitation with a variety of visible and ultraviolet light sources.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over West in view of Maine as applied to claim 26 above, and further in view of Fray.

West and Maine have been discussed above.

However, they fail to teach associating the metal particle to the first binding member in the presence of lithium chloride.

Fray teaches using lithium chloride salt to as a salt of a metal surface to be refined. Such salt when saturating the metal surface allows the metal ions to move through freely. (see col. 1, lines 27-40).

It would have been obvious to one of ordinary skills in the art to use lithium chloride as taught by Fray as an enhancer for the metal surface in the assay mixture as in the method of West modified by Maine since this salt is used for refining metal surface and it keeps the metal ions on the metal surface intact or prevents the metal ions on the metal surface from being wear off. Since West's nanoshell is a metal

Art Unit: 1641

nanoshell, such salt would advantageously prevent the metal of the nanoshell from being worn off.

Claims 24 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over West in view of Maine as applied to claims 22 and 31 above, and further in view of Tarcha (US 5,376,556).

West and Maine have been discussed above.

However, they fail to teach detecting antibody fragments.

Tarcha teaches a SERS assay for detecting antibody fragments. The first and second specific binding member is a protein, antibody molecule or fragment thereof, receptor and ligand, nucleic acid molecules. (see col. 33-54).

It would have been obvious to one of ordinary skills in the art to detect antibody fragments as taught by Tarcha in the method of West modified by Maine so that a wide variety of analytes can be detected since it is known that Ab fragments can be used in SERS assay as illustrated by Tarcha.

Response to Arguments

Applicant's arguments in the Appeal Brief and After-final amendment with respect to claims 1-16, 19-34 have been considered but are moot in view of the new ground(s) of rejection.

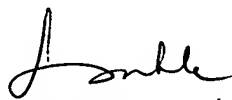
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
October 11, 2007


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